UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

MARK HABELT, et al.,

Plaintiffs,

v.

IRHYTHM TECHNOLOGIES, INC., et al.,

Defendants.

Case No. 21-cv-00776-EMC

ORDER GRANTING DEFENDANTS' MOTION TO DISMISS

Docket No. 55

Lead Plaintiff Public Employees' Retirement System of Mississippi brings this class action on behalf of similarly situated investors against Defendant iRhythm and Individual Defendants King, Coyle and Devine (current or former corporate officers of iRhythm) to recover damages for Defendants' alleged violations of federal securities laws.

Now pending is Defendants' motion to dismiss Plaintiffs' Second Amended Complaint ("SAC") in its entirety for failure to state claims, pursuant to Fed. R. Civ. P. 12(b)(6). Docket No. 55 ("MTD"). For the following reasons, the Court **GRANTS** Defendants' motion.

I. BACKGROUND

A. Relevant Factual Allegations

1. iRhythm's Business

Defendant iRhythm is a "digital healthcare company that focuses on providing long-term ambulatory electrocardiogram ("AECG") devices" designed to "diagnose cardiac arrythmias." Docket No. 54 ("SAC") ¶ 2. AECG devices can provide up to 14 days of electrocardiographic data which is "scanned and analyzed by [iRhythm's] cardiac technicians, and then presented in a report to a doctor for diagnosis." *Id.* iRhythm's core AECG product is allegedly the Zio XT

patch, from which the company allegedly derives "over 85% of its total revenue." *Id.* iRhythm's revenue from the Zio XT patch is allegedly "directly or indirectly tied to Medicare reimbursement rates." *Id.* ¶ 3. "At least 25% of the Company's total revenue was tied to servicing Medicare patients" and the remaining sales to commercial payors were allegedly "indirectly tied to Medicare reimbursement rates" because those customers "typically pay between 1.5 times to 2 times the rate set by the [Centers for Medicare and Medicaid Services ("CMS")] in a Medicare Physician Fee Schedule ("PFS" released annually." *Id.*

CMS requires reimbursed services to be billed pursuant to "Current Procedural Technology" ("CPT") codes, which are assigned corresponding prices. *Id.* ¶ 4. Prior to 2021, iRhythm billed for its Zio XT service under temporary CPT codes—called Category III codes—which are used for newly-introduced technologies. *Id.;* MTD at 13. CMS delegates the reimbursement pricing rates for Category III codes to regional Medicare Administrative Contractors ("MACs"). Novitas, the MAC that oversees pricing for iRhythm's Zio XT services, set the Category III rates for Zio XT between $311 and $316 for several years prior to 2021. SAC ¶ 4, 57.

2. Recommendation of Zio XT for Permanent Pricing and CMS's Proposed Rule

The American Medical Association ("AMA"), which has a role in maintaining CPT codes, recommended that CMS adopt a permanent Category I CPT code for the Zio XT service in 2021, indicating its view that the service had become the "standard of care." *Id.* ¶ 56. The process by which a Category III temporary CPT code is adopted into a Category I permanent code involves the AMA's Resource-Based Relative Value Scale Update Committee ("RUC") providing a recommendation of pricing to CMS. *Id.* While CMS "gives weight to the RUC's input and recommendations, it is not obligated to accept the RUC's recommendation in the final rule, and it can modify pricing based on its own analysis or delegate pricing to MACs in the final rule." *Id.*

Based on the RUC's recommendation, CMS proposed a rule with reimbursement rates of $375.83 and $386.16 for Category I CPT codes for External Extended ECF Monitoring, including the Zio XT, to go into effect in January 2021. *Id.* ¶ 62. The proposed rule noted that CMS "did not receive a traditional invoice to establish a price for this supply item," 85 Fed. Reg. 50165

(August 17, 2020), allegedly because "iRhythm declined to submit actual invoices, instead providing CMS with insurance claim and cost data that showed only the total cost charged to third-party payors" which includes, among other expenses, the cost of iRhythm's service to analyze data collected by the Zio XT patch, "without any breakdown of the cost of the different components of the Zio XT," SAC ¶ 68.

CMS observed that rather than receiving traditional invoices, it received alternative forms of pricing information, including a weighted median of historical billed prices for the service, a top-down calculation of the cost of the supply per service, and invoices provided from clinical studies. 85 Fed. Reg. 50165. CMS noted that it requires "an invoice representative of commercial market pricing to establish a national price for a new supply or equipment item," and, therefore, based on the data that was made available to the agency, it "cannot establish supply pricing based on an analysis of claims data and in absence of a representative invoice." *Id.* Instead, CMS proposed to employ a "crosswalk to an existing supply for use as a proxy price until [it obtained] and invoice to use." *Id.* CMS explained that although the proxy item it identified was "not clinically similar to the extended external ECG patch," the agency "believe[d] it [was] the closest match from a pricing perspective to employ as a proxy until [CMS was] able to arrive at an invoice that is representative of commercial market pricing." *Id.* at 50165-66. The proposed rule was followed a public notice-and-comment period. SAC ¶ 59, 64.

3. MCDA's October 2020 Comment

On October 5, 2020, MCDA, a healthcare policy and consulting firm based in Washington, D.C., filed a report to CMS as a comment on its proposed rulemaking, urging the agency to adopt a significantly lower CPT Category I price for extended external ECG's patches, including the Zio XT. *Id.* ¶¶ 63-99. The report argued (1) that the true cost of Zio XT was less than $100 because iRhythm had folded indirect, un-reimbursable expenses for research and development, and sales and advertising into their costs, *id.* ¶¶ 65-70; (2) the proxy device CMS relied on for pricing purposes was more complex, and, therefore, an inapposite comparator, *id.* ¶¶ 71-74; (3) an invoice from a device developed by one of iRhythm's direct competitors of an allegedly similar device indicated that the reimbursement rate should be no more than $85.21, *id.* ¶¶ 88-89; and (4) senior

executives in the industry allegedly were aware that the cost of the monitoring device is a small fraction of CMS's proposed rate and the price of the hardware was trending downwards, *id.* ¶¶ 94-96. iRhythm filed a three-page response to the MCDA report which, allegedly, did not contest MCDA's analysis. *Id.* ¶¶ 100-03.

4. CMS Final Rule and Pricing for 2021

On December 1, 2020, CMS released its Final Rule establishing payment rates for AECG monitoring devices for the calendar year 2021. The agency, however, declined to set a national reimbursement rate for the devices because it lacked "an invoice representative of commercial market pricing." 85 Fed. Reg. 84632 (Dec. 28, 2020). The Final Rule acknowledged its decision not to set a national rate was based, in part, on "the conflicting information and assertions provided by commenters" during the notice-and-comment period and declined to establish pricing based on the proxy device it previously identified. *Id.* at 84633-34. CMS maintained Category I CPT codes for AECG devices, allowing those services to be provided and billed to Medicare patients, but it delegated pricing for those codes to the regional MACs for 2021. SAC ¶ 105. Thus, Novitas remained responsible for determining the reimbursement rates for Zio XT in 2021. *Id.*

Plaintiffs allege that iRhythm's stock price declined after CMS released its final rule from $240.64 on December 1, 2020 to $180.90 by the end of trading on December 4, 2020. *Id.* ¶ 106.

After CMS delegated the rate-setting decision for 2021 to Novitas, MCDA allegedly published another report arguing that iRhythm's proposed pricing lacked support. SAC ¶¶ 108-21. Plaintiffs allege their independent expert, Dr. Freeman, independently corroborated MCDA's analysis. *Id.* ¶¶ 122-30.

On January 29, 2021, Novitas announced reimbursement rates for Zio XT that slashed the historical rate of $311 to a range of average rates of $73.82 to $89.36. *Id.* ¶ 135. Plaintiffs allege that this announcement caused iRhythm's stock price to drop from $251 on January 28 to $168.42 on January 29, 2021. *Id.* ¶ 136.

On April 10, 2021, Novitas revised to rate upward to $115. *Id.* ¶ 139. Plaintiffs allege that this news caused iRhythm's stock price to drop from $132.76 on April 9 to $80.36 on April 12,

2021. *Id.* ¶ 140.

5. Proposed and Final Rule for 2022

On July 13, 2021, CMS released the proposed rule for CPT pricing effective January 1, 2022, and noted its concern with regards to External Extended ECG Monitoring that "supply costs as initially considered in [its] CY 2021 PFS proposal are much higher than they should be" and sought public comment regarding "fair and stable pricing for these services." SAC ¶ 145. Plaintiffs allege that iRhythm's stock price dropped from $59.07 to $53.90 after the proposed rule was released. *Id.* ¶ 147.

Defendants cite to CMS's final rule for 2022, which declined to set national pricing, but endorsed a rate of $200.15 for devices, including the Zio XT, for consideration by MACs in setting rates for 2022. 86 Fed. Reg. 65125 (Nov. 19, 2021). Novitas ultimately adopted a rate in excess of $210 for 2022. See Docket No. 59-1, Exh. 24.

6. Timeline of Events

For convenience, the relevant factual allegations are summarized in the timeline below:

Date	Description of Event
Prior to 2020	iRhythm billed for its Zio XT service under temporary, Category III, CPT codes for newly-introduced technologies. The rate ranged between $311 and $316. SAC ¶¶ 4, 57.
Aug. 3, 2020	CMS publicly released a **proposed** rule adopting the recommendation of the American Medical Association to set a permanent CPT code and corresponding reimbursement rate for the Zio XT service between $375.83 and $383.16, to go into effect in January 2021. SAC ¶¶ 62, 68. CMS noted that the proposed rate was based on an a "crosswalk" to a proxy item, because the agency had not received "traditional invoices" from which it could generate pricing under its typical pricing model.
Aug. - Oct. 2020	CMS's proposed rule was subject to a public notice-and-comment period.
Oct. 5, 2020	MCDA, a healthcare policy and consulting firm, filed a public comment on CMS's proposed rulemaking in which it argued that the proposed rate for the Zio XT service was inflated, and that the rate should not be more than $85.21. MCDA argued that the proposed rate in excess of $300 far exceeded the true cost of the Zio XT service, and reimbursed iRhythm for impermissible expenses, such as a marketing and research costs. SAC ¶¶ 63-99.

Date	Description of Event
Dec. 1, 2020	CMS publicly released its Final Rule establishing payment rates for AECG monitoring devices for 2021. The agency declined to set a national, permanent rate because it "lacked an invoice representative of commercial market pricing." Rather than set a rate, CMS delegated the rate-setting for 2021 to the regional MACs, including Novitas, which had previously been responsible for setting the reimbursement rate for Zio XT. SAC ¶ 105.
Dec. 4, 2020	iRhythm's share price allegedly declined from $240.64 on Dec. 1 to $180.90 on Dec. 4. SAC ¶ 106.
Jan. 29, 2021	Novitas announced reimbursement rates for Zio XT that slashed the historical rate of $311 to a range of average rates between $73.82 to $89.36. SAC ¶ 135.
Jan. 29, 2021	iRhythm's share price allegedly declines from $251 on January 28 to $168.42 on January 29. SAC ¶ 136.
Apr. 10, 2021	Novitas announced an upward revision of the reimbursement rate for Zio XT from an average of $73.82 to $115. SAC ¶ 139.
Apr. 12, 2021	iRhythm's share price allegedly declines from $132.76 on April 9 to $80.36 on April 12. SAC ¶ 140.
Jul. 13, 2021	CMS publicly releases its proposed rule for reimbursement rates effective January 1, 2022. In that proposed rule, it declined to propose a rate for devices like the Zio XT, noted concerns that animated the pricing decision from the previous year, and sought public comment regarding fair and stable pricing for such services. SAC ¶ 145.
Jul. 13, 2021	iRhythm's share prices allegedly declines from $59.07 to $53.90 upon release of the CMS proposed rule. SAC ¶ 147.
Nov. 19, 2021	CMS publishes its final rule for rate setting for 2022. Although CMS declined to set a national rate, it endorsed a rate of $200.15 for the Zio XT to be considered by MACs, including Novitas. 86 Fed. Reg. 65125.
Jan. 2022	Novitas adopts a reimbursement rate of $210 for Zio XT for the 2022 calendar year.

7. Allegations of Defendants' Violations of Securities Law

Plaintiffs allege Defendant iRhythm and Individual Defendants Kevin King, Michael Coyle and Douglas Devine, who each held the position of CEO of iRhythm for periods of time between August 2020 and June 2021, made 18 false or materially misleading statements in violation of federal securities law regarding iRhythm's engagement in the regulatory price-setting process and Defendants' knowledge of the risks that the company faced. *See* SAC ¶¶ 148-182; Appendix A, Challenged Statement Chart (collecting and numbering Plaintiffs' allegations of false statements).

Plaintiffs further allege Defendants' scienter is evidenced by (1) CMS's past practice rejecting pricing methodologies like the one iRhythm proposed, *id.* ¶¶ 184-196, (2) witness

testimony from a contract dispute between iRhythm's competitors, *Birdy Diagnostics, Inc. v. Hill-Rom, Inc.*, No. 2021-175-JRS (Del. Ch. 2021), indicating knowledge among industry participants of the likelihood of a rate cut, *id.* 189-97, (3) allegations by Confidential Witness 1, iRhythm's former Executive Vice President of Payer Relations and Market Access, that iRhythm was unlikely to succeed in maintain its Category III pricing when its technology was adopted as a Category I service, *id.* ¶¶ 198-205, (4) iRhythm's misrepresentations involved its core operations, *id.* ¶¶ 206-08, (5) Defendants held themselves out as knowledgeable about the regulatory landscape, *id.* ¶¶ 209-212, (5) iRhythm's failure to seriously contest MCDA's October 2020 report, *id.* ¶ 213, and (6) Defendant King's alleged insider sales of his shares in the company at inflated prices, *id.* ¶¶ 214-16.

8. Class Allegations and Causes of Action

Lead Plaintiff seeks to represent a class under Fed. R. Civ. P. 23(b)(3) on "behalf of all persons or entities that purchased or otherwise acquired iRhythm's common stock between August 4, 2021 and July 13, 2021 (the 'Class Period')." SAC ¶ 217. Lead Plaintiff alleges an "average monthly volume of 11.2 million shared" were traded during the Class period and that there are "several hundreds if not thousands of members" in the proposed class. Id. ¶ 218.

The SAC alleges two counts. First, as to all Defendants, the SAC alleges violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated by the SEC. SAC ¶¶ 226-35. Plaintiffs allege that Defendants engaged in a plan to deceive the investing public, artificially inflate and maintain the market price of iRhythm common stock, and cause Plaintiffs to purchase iRhythm stock at artificially inflated prices. *Id.* Second, as to Individual Defendants King, Coyle and Devine, the SAC alleges violations of Section 20(a) of the Exchange Act based on their status as controlling persons of iRhythm and their alleged predicate violations of the Exchange Act in Count 1. SAC ¶¶ 236-42.

B. Procedural Background

Plaintiff filed this action on February 1, 2021. Docket No. 1. On June 1, 2021, the Court granted Public Employees' Retirement System of Mississippi's motion for appointment as lead counsel. Docket No. 39. Lead Plaintiff filed an amended complaint on August 2, 2021. Docket

No. 41. The Court granted the parties' stipulation for Lead Plaintiff to file a second amended complaint. Docket No. 53. Lead Plaintiff filed its second amended complaint on September 24, 2021. Docket No. 54.

Now pending is Defendants' motion to dismiss the second amended complaint. Docket No. 55 ("Motion").

II. STANDARD OF REVIEW

A. Failure to State a Claim (Rule 12(b)(6)

Federal Rule of Civil Procedure 8(a)(2) requires a "pleading that states a claim for relief" to include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A pleading that fails to meet this standard may be dismissed pursuant to Rule 12(b)(6). *See* Fed. R. Civ. P. 12(b)(6). To overcome a Rule 12(b)(6) motion to dismiss after the Supreme Court's decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544 (2007), a plaintiff's "factual allegations [in the pleading] 'must . . . suggest that the claim has at least a plausible chance of success.'" *Levitt v. Yelp! Inc.*, 765 F.3d 1123, 1135 (9th Cir. 2014). The court "accept[s] factual allegations in the [pleading] as true and construe[s] the pleadings in the light most favorable to the nonmoving party." *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). But "allegations in a [pleading] . . . may not simply recite the elements of a cause of action [and] must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively." *Levitt*, 765 F.3d at 1135 (quoting *Eclectic Props. E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 996 (9th Cir. 2014)). "A claim has facial plausibility when the Plaintiff pleads factual content that allows the court to draw the reasonable inference that the Defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556). As discussed below, heightened particularity is required under Fed. R. Civ. P. 9(b) and the Private Securities Litigation Reform Act.

III. DISCUSSION

Defendants raise three arguments in support of dismissal of the SAC: (1) the challenged statements are not actionable under federal securities law; (2) Lead Plaintiff fails to plead facts sufficient to establish a strong inference of scienter; and (3) there are insufficient allegations to establish loss causation. In support of their arguments, Defendants also request judicial notice of several documents. Docket No. 56 ("RJN").

A. Request for Judicial Notice (Docket No. 56)

Defendants request that the Court incorporate by reference or take judicial notice of 25 documents. See Docket Nos. 55-1 ("Seite Decl."), 56 ("RJN"), 59-1 ("Suppl. Seite Decl.").

When ruling on a Rule 12(b)(6) motion to dismiss, in addition to the entirety of the complaint, courts may consider (1) "documents incorporated into the complaint by reference" and (2) "matters of . . . judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd*., 551 U.S. 308, 322 (2007). Under the doctrine of incorporation by reference, courts are permitted to consider a document "if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim." *Khoja v. Orexigen Therapeutics, Inc*., 899 F.3d 988, 1002 (9th Cir. 2018) (quoting *United States v. Ritchie*, 342 F.3d 903, 907 (9th Cir. 2003)). A single reference to a document in a complaint can be enough for the document to be incorporated if the reference is "relatively lengthy." *Id*. at 1003. Courts may consider the full text of incorporated documents "including portions which were not mentioned in the complaints" in a ruling on a motion to dismiss. *In re Stac Elecs. Sec. Litig*., 89 F.3d 1399, 1405 n.4 (9th Cir. 1996). Under the doctrine of judicial notice, courts may consider information "not subject to reasonable dispute because it: (1) is generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). The Court may consider such facts "at any stage of the proceeding," Fed. R. Evid. 201(d), "even if they are not referenced in the pleading, so long as they meet the requirements for judicial notice set forth in Federal Rule of Evidence 201." *Cement Masons & Plasterers Joint Pension Tr. v. Equinix, Inc*., 2012 WL 685344, at *8 n.5 (N.D. Cal. Mar. 2, 2012). Among other things, courts in the Ninth Circuit routinely take judicial notice of: (i) documents filed with public authorities,

e.g., *Metzler Inv. GMBH v. Corinthian Colls., Inc*., 540 F.3d 1049, 1064 n.7 (9th Cir. 2008) (noting it "was proper" for the district court to judicially notice SEC filings) and (ii) documents published by the government itself, *e.g.*, *Anschutz Corp. v. Merrill Lynch & Co*., 785 F. Supp. 2d 799, 834 (N.D. Cal. 2011) (taking judicial notice of congressional hearing testimony).

As a threshold matter, Lead Plaintiff does not oppose Defendants' request to consider the contents of Exhibits 10-14, which are CMS rules and MCDA's October 5, 2020 and December 30, 2020 reports commenting on the rules. Additionally, Lead Plaintiff does not object to the Court's consideration of similar exhibits, Exhs. 22 (CMS Final Rule, Nov. 19, 2021) and 24 (publicly available disclosure of Novitas's rate set for relevant CPT codes for 2022 pursuant to CMS's Final Rule), which were entered in support of Defendants' reply brief. Plaintiff neither filed an evidentiary objection, nor did Plaintiff contest the Court's consideration of those documents or the authenticity of the documents in its Sur-Reply, which the Court granted leave to file. Docket No. 62-1. Plaintiff argues that this information does not support Defendants' arguments on the merits, but do not object to the Court's consideration of the documents. *Id*. These documents satisfy Fed. R. Evid. 201. The Court takes judicial notice of Exhibits 10-14, 22, 24.

Next, the Court determines Exhs. 6-9, 21, 23, investor call transcripts which are extensively quoted by the SAC, are incorporated by reference. *See e.g*., SAC ¶¶ 148, 149, 209 (quoting August 4, 2020 call, Exh. 9); *id.* ¶¶ 154, 155, 209 (quoting August 13, 2020 call, Exh. 8); *id.* ¶¶ 156, 157 (quoting Nov. 5, 2020 call, Exh. 7); id. ¶¶ 11, 158-61, 163-68 (quoting December 2, 2020 call, Exh. 6); *id.* ¶ 174 (April 12, 2021 call, Exh. 21); *id.* ¶ 169 (quoting Feb. 25, 2021 call, Exh. 23). Courts in this district routinely consider investor call transcripts under this doctrine. *See In re SunPower Corp. Sec. Litig*., 2018 WL 4904904, at *3 n.2 (N.D. Cal. Oct. 9, 2018) (incorporating investor call transcripts by reference under *Orexigen*); *Yaron v. Intersect Ent, Inc*., 2020 U.S. Dist. LEXIS 219448, at *8 (N.D. Cal. June 19, 2020) (same); *McGovney v. Aerohive Networks, Inc.*, 367 F. Supp. 3d 1038, 1051 (N.D. Cal. 2019) (considering earnings call transcripts and SEC filings as incorporated by reference into the complaint); *In re Fusion-io, Inc. Sec. Litig*., 2015 WL 661869, at *9 (N.D. Cal. Feb. 12, 2015) (treating SEC filings and earnings call transcripts as "part of the complaint" and assuming their "contents are true for purposes of a

motion to dismiss") (citation omitted).

The Court takes judicial notice of Exhs. 1-5, 18, 25, which are SEC filings on Forms 4, 8-K, 10-Q, and 10-K that show publicly available information about iRhythm. *See Metzler*, 540 F.3d at 1064 n.7; *Weller v. Scout Analytics, Inc*., 230 F. Supp. 3d 1085, 1094 & n.5 (N.D. Cal. 2017) (judicial notice of Form 10-K is generally appropriate in securities fraud case); *Yamauchi v. Cotterman*, 84 F. Supp. 3d 993, 1014 n.13 (N.D. Cal. 2015) (granting a request for judicial notice of a Form 8-K because "[a] filing with the SEC is the type of public record that comes from a source whose accuracy cannot reasonably be questioned").

Defendants' remaining requests for judicial notice are denied as moot because it is unnecessary for the Court to refer to those documents to decide the pending motion.

B. Legal Framework for Securities Fraud

Rule 10b–5, which implements the anti-fraud provisions of section 10(b) of the Securities Exchange Act, makes it "unlawful for any person, directly or indirectly, by the use of any means or instrumentality of interstate commerce, or of the mails or of any facility of any national securities exchange ... [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading." 17 C.F.R. § 240.10b–5. To state a claim for securities fraud, a complaint must allege:

> (1) a material misrepresentation or omission by the defendant;
>
> (2) scienter;
>
> (3) a connection between the misrepresentation or omission and the purchase or sale of a security;
>
> (4) reliance upon the misrepresentation or omission;
>
> (5) economic loss; and
>
> (6) loss causation.

Halliburton Co. v. Erica P. John Fund, Inc., 134 S.Ct. 2398, 2407 (2014) (citations omitted). At issue in this motion are the first, second and sixth elements: material misrepresentations or omissions, scienter and loss causation.

To state a claim for securities fraud, a plaintiff must also satisfy the heightened pleading requirements of Rule 9(b) and the Private Securities Litigation Reform Act ("PSLRA"). *Police Ret. Sys. v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1057–58 (9th Cir. 2014). "Due in large part to the enactment of the [PSLRA], plaintiffs in private securities fraud class actions face formidable pleading requirements to properly state a claim and avoid dismissal[.]" *Metzler Inv. GMBH v. Corinthian Colls., Inc.*, 540 F.3d 1049, 1054–55 (9th Cir. 2008). To satisfy these requirements, a complaint must: (i) "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief . . . state with particularity all facts on which that belief is formed," 15 U.S.C. § 78u-4(b)(1)(B); and (ii) "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind," or scienter, *id.* § 78u-4(b)(2).

With respect to scienter, "[t]he inquiry. . . is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 323 (2007). "To determine whether the plaintiff has alleged facts that give rise to the requisite 'strong inference' of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 323-24. "[T] the inference of scienter must be more than merely 'reasonable' or 'permissible'—it must be cogent and compelling, thus strong in light of other explanations." *Id.* at 324.

C. Material Misrepresentations or Omissions

Lead Plaintiff alleges Defendants made 18 statements that constituted material misrepresentations or omissions. *See* Appendix A. To meet the materiality requirement of Rule 10b–5, the SAC must allege facts sufficient to support the inference that there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Basic Inc. v. Levinson*, 485 U.S. 224, 231–32 (1988) (internal quotation marks omitted).

Defendants argue that the 18 statements are not actionable for five reasons: (1) the challenged statements were made in the context of a public regulatory proceeding, (2) iRhythm's

forward-looking statements are protected by the PSLRA's safe harbor, (3) many of the statements are nonactionable opinions, (4) the challenged statements of corporate optimism are non-actionable puffery, and (5) the remaining statements fail to state a claim because they are neither misrepresentations nor material.

1. Statements in the Context of Regulatory Proceedings

Defendants observe that the "[t]he crux of the SAC is the claim that Defendants failed to 'come clean' with investors about the purportedly undisclosed 'threats' and 'risks' that iRhythm faced in its efforts to increase or maintain Medicare reimbursement rates for the new Category I codes." Motion at 17. Accordingly, Defendants argue that the allegations in the SAC must be analyzed through the lens of the Ninth Circuit's precedent that corporate statements made in the context of regulatory proceedings do "not ordinarily invoke a duty to disclose or provide a basis for a securities fraud claim." *Epstein v. Washington Energy Co.*, 83 F.3d 1136, 1141-42 (9th Cir. 1996).

The analysis in *Epstein* is largely on point and guides the Court's analysis of the challenged statements here. *Epstein* involved allegations of securities fraud under Section 10(b) and Rule 10b-5 against a regulated public utility company with regard to the company's alleged failure to disclose certain information that could bear on the likelihood that the company would obtain a regulatory rate increase while the company awaited a decision on the rate request from a state agency. *Id.* at 1137. Specifically, Plaintiffs "assert[ed] that Defendants failed to disclose: 1) that the [state agency] had previously disapproved of Defendants' wrongful allocation of costs and attempts to subsidize unregulated operations, and 2) that the 1992 rate increase request was predicated on the same condemned practices." *Id.* at 1140. The court rejected Plaintiffs' arguments.

It reasoned that "[t]he regulatory process by which a public utility rate is fixed and the effect of that process on a utility stock's market value are materially different from the way an efficient market digests relevant information and renders decisions regarding the value of other securities." *Id.* at 1141. For example, "[t]he application for a rate increase is a matter of public record," "[r]ate making proceedings are formal, formatted, controlled by unique rules and

considerations, and public," and, ultimately, the "administrative proceeding before an independent state commission" yields a decision by the commission "which is dispositive of the rate." *Id.* Accordingly, the court observed, "[i]n this unique context, the kind of the information claimed to be fraudulent, such as misleading predictions about the final rate decision, awaits a different kind of arbiter than the unseen hand of the market." *Id.* "As such, anyone. . . attempting to predict the judgment of the intermediate arbiter engages, by definition, in a problematic exercise distinguishable from the normal investment decision." *Id.* Therefore, *Epstein* concluded that,

> **[R]eliance on predictive statements in the context of regulatory proceedings is inherently unreasonable.** Basing **an investment decision on an anticipated and contingent outcome of a litigated regulatory proceeding, even *with* full knowledge of the prior history of the parties, is tantamount to sheer speculation; and guessing wrong hardly suggests fraud**. Accordingly, an investor who relies on such information cannot be said to be misled by an "untrue statement of material fact." The context of the regulatory process does not ordinarily invoke a duty to disclose or provide a basis for a securities fraud claim. **Thus, a utility that has announced it has submitted an application for a rate increase normally has no duty to inform the public of any facts or circumstances in addition to those set forth in the application.**

Id. at 1141-42 (internal citation omitted) (emphases added). Applying this framework to the facts in *Epstein,* the court explained that "[Defendant] had clearly stated that the rate increase proposal was pending before the [state commission], and that any additional future revenues depended on the [commission's] approval of the rate increase," and, thus, "it is evident that the market was alerted to the regulatory nature of the proceedings." *Id.* at 1142. The court concluded that, "Once the market had been so alerted, [Defendant] did not have a duty to disclose further information about the rate making proceedings," and held, "[t]herefore, the alleged omissions do not provide a basis for a Rule 10b–5 claim." *Id.*

Although there are some factual differences between *Epstein* and the case at bar–iRhythm is not a regulated utility company, CMS's notice-and-comment process and appears to differ from the "litigated regulatory proceeding" in *Epstein*—these facts do not undermine the applicability of *Epstein's* analysis in support of its conclusion that "reliance on predictive statements in the context of regulatory proceedings is inherently unreasonable" or the principle that once a defendant has alerted the market to pending regulatory proceedings that will determine the

relevant rate the company will obtain, the company does "not have a duty to disclose further information about the rate making proceedings." *Id.* at 1141-42. It is undisputed that Defendants' challenged statements were made during the pendency of public regulatory proceedings before a governmental agency, CMS, regarding the agency's decision as to the reimbursement rates Defendants would receive for its Zio XT service. The reimbursement rate application was publicly available through the American Medical Association's RUC. SAC ¶ 56. Lead Plaintiff's central theory of fraud relates to Defendants' conduct during the regulatory process and, at bottom, amounts to a challenge to the sufficiency of Defendants' disclosures regarding the risks that Defendants faced in obtaining a favorable decision through the regulatory process. Thus, *Epstein* applies here. 83 F.3d at 1141.

Indeed, Lead Plaintiff does not dispute the analysis in *Epstein* or contend that *Epstein*, on its face, would not apply to iRhythm or the regulatory proceedings here. Lead Plaintiff does not offer any analysis to dispute the applicability of *Epstein* other than to attempt to distinguish it in passing by asserting that "[t]his is not a case where Plaintiff faults Defendants for making misleading predictions about the final rate decision." Docket No. 57 ("Opp.") at 20. But, in fact, Lead Plaintiff alleges many of Defendants' statements were false or misrepresentations *precisely* because Defendants' predictions about the likelihood the company would obtain a favorable final pricing decision by CMS or Novitas were misleading.[1]

[1] *See* SAC § Appendix, Statements Nos. 1 ("Reason Why False: "King was already informed but concealed that. . . the company would face major challenges with its current reimbursement strategy going forward" and "King knew that the rates set by Novitas were an outlier"), 3 (same as 1), 4 (same as 1, and "the risk of an adverse ruling from CMS remained very high"), 5 (same as 1, and "King failed to disclose. . . that the release of MCDA's Report in the notice-and-comment period had put the excessively high reimbursement rates for the Zio XT at risk"), 6 ("Reason Why False. . . the local contracting path was not 'attractive,' but was in fact undermined by proof contained in the October 5, 2020 MCDA Report that the inflated reimbursement rates previously under consideration for the Zio XT were grossly inflated"), 7 ("Reason Why False… [CMS's final 2021 rule was] effectively a rate cut, as CMS indicated it could not substantiate the inflated rate under consideration"), 8 ("Reason Why False…there were multiple bases for them lowering reimbursement rates"), 10 ("See reasons provided above in connection with Statements #6, 7, 8), 11 ("Reason Why False. . . Coyle knew, but failed to disclose. . . that the Company could not collect all of its indirect costs for the Zio XT device."), 13 (same as 11), 14 ("Reason Why False. . . [iRhythm] faced an uphill battle that was almost certainly bound to fail after the revised rates were released in April 2021."), 15 (same as 11), 16 ("Reason Why False. . . industry experts had already concluded that Novitas was an outlier amongst the MACs and its past high rats for the Zio XT were a huge red flag."), 17 (same as 11), 18 (same as 11, and "the Company was, in fact,

Indeed, Lead Plaintiff's arguments that iRhythm wrongfully withheld information that the pricing methodology the company submitted to CMS and Novitas was disfavored and unlikely to succeed in obtaining the reimbursement rate that iRhythm sought are of the same nature of the arguments that *Epstein* rejected as beyond the scope of the company's duty to disclose and dismissed for failure to state claims. *See Epstein*, 83 F.3d at 1140 (rejecting Section 10(b) claims on the basis of "Plaintiffs['] assert[ions] that Defendants failed to disclose: 1) that the WUTC had previously disapproved of Defendants' wrongful allocation of costs and attempts to subsidize unregulated operations, and 2) that the 1992 rate increase request was predicated on the same condemned practices."); *see also* 83 F.3d at 1142 ("Here, WEC's alleged omissions related to the specific accounting methods on which it predicated its rate increase proposal and the past failure of similar proposals. . . [T]he alleged omissions do not provide a basis for a Rule 10b-5 claim.").

Moreover, just as the Defendant in *Epstein* "clearly stated that the rate increase proposal was pending before the [state commission] and that any additional future revenues depended on the approval of the rate increase," *id.* at 1142, so too did iRhythm here, *see e.g.*, Docket No. 55-1, Exh. 3 ("Form 10-Q" filed with SEC on August 7, 2020) at 43 ("[W]e are and will continue to be subject to changes in the level of Medicare coverage for our produces, and unfavorable coverage determinations at the national or local level could adversely affect our business and results of operations"), *id.* ("We can provide no assurance that any Category I CPT code secured for the reimbursement of our Zio service will contain values and pricing that are the same as or greater than the existing Category III CPT codes. In addition, to the extent CMS reduces its reimbursement rates for the Zio service, regardless of the Category of CPT code, third-party payors may reduce the rates at which they reimburse the Zio service, which could adversely affect our revenue."), *id.* ("Reductions in reimbursement rates, if enacted, could have a material adverse effect on our business. Further, a reduction in coverage by Medicare could cause some commercial third-party payors to implement similar reductions in their coverage or level of reimbursement of the Zio service."), *id.* at 44 ("If third-party commercial payors do not provide

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trying to break new ground with its attempt to seek impermissibly, indirect costs from CMS").

adequate reimbursement, rescind or modify their reimbursement policies or delay payments for our products, including out Zio service, or if we are unable to successfully negotiation reimbursement contracts, our commercial success could be compromised.").

Thus, like in *Epstein*, Lead Plaintiff cannot state claims under Section 10(b) to the extent its claims are based on allegations that Defendants failed to disclose "information [that] was part of the regulatory process" or made "misleading predictions about the final rate decision." 83 F.3d at 1141, 1142. Thus, because Challenged Statements 1, 3-8, 10-11 and 13-18 focus on Defendants' predictions as to the outcome of the regulatory process, they are not actionable under *Epstein*.

Lead Plaintiff, however, also advances specific allegations of false statements or material misrepresentations in Challenged Statements 2, 9 and 12 that are not categorically swept away from the application of *Epstein*. Additionally, the statements that are unactionable under *Epstein* are also unactionable for independent reasons. Further analysis is required.

2. PSLRA's Safe Harbor for Forward-Looking Statements

Defendants argue that they are immunized from liability for Statement Nos. 1, 3-11, and 13-18 under the PSLRA's safe harbor provision.

The PSLRA's safe harbor provision exempts a forward-looking statement, which is "any statement regarding (1) financial projections, (2) plans and objectives of management for future operations, (3) future economic performance, or (4) the assumptions underlying or related to any of these issues." *Police Ret. Sys. of St. Louis v. Intuitive Surgical, Inc.*, 759 F.3d 1051, 1058 (9th Cir. 2014) (*citing No. 84 Emp'r–Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp.*, 320 F.3d 920, 936 (9th Cir. 2003)).

The PSLRA immunizes forward-looking statements in two ways: (1) "if they were identified as forward-looking statements and accompanied by meaningful cautionary language"; or (2) if plaintiffs "fail to prove [they] were made with actual knowledge that they were materially false or misleading[.]" *Park v. GoPro, Inc.*, 2019 WL 1231175, at *15 (N.D. Cal. Mar. 15, 2019) (citation omitted). Where a forward-looking statement is accompanied by meaningful cautionary language, the state of mind of the person making the statement is irrelevant. *Id.*

a. Forward-Looking

Defendants contend that Statement Nos. 1, 3-11, and 13-18 are "forward-looking" because they are statements regarding "plans and objectives of management for future operations" as well as "assumptions underlying or relating to" any such statement. Motion at 17-18. They argue that each statement is connected to "possible outcomes of reimbursement rate setting, the impact that reimbursement rates could have on iRhythm's non-Medicare commercial business; and the Defendants' views on the progress of discussions with MACs and CMS regarding reimbursement rates." *Id.*

Defendants' categorization of these statements as forward-looking self-evident from the face of those statements.[2]

[2] *See* Appendix A, Statement Nos. 1 ("I think that calculation was done well, and we'll support it. And I'm confident it's what CMS wanted, and that's where we've got the rates. I'm not concerned about that changing."), 3 ("As far as the code structure side, the process was so to thorough and so complete, I'm hoping that there's not much to change. But of course, there's the comment period. And we'll see what happens."), 4 ("We've always been confident that our reimbursement rate will be the same or go up. And we believe, it stood the evidence in the fact base that we have. So, we're really happy with that. It is an initial ruling, so there's a comment period that takes place between and now and sometime in early December, before it becomes final."), 5 ("We remain extremely confident in where we sit. . . and we're looking very forward to December 1st when the final ruling takes place."), 6 ("We believe our commercial contract pricing is unaffected, as is our ability to pursue Medicaid contracting and reimbursement for our home enrollment service. . . [T]he CPT codes remain and we believe this positions us well to improve patient access and physician willingness to adopt the technology."), 7 ("I think the challenge is. . . CMS has a rather rigid framework that requires precise inputs like an invoice that don't exist in these categories. And it's our job to help them to remodel or to affect change such that not only iRhythm, but every other digital health company. . . can get the benefit of fairly valued renumeration."), 8 ("We're going to be shooting for that, for the higher end of where we were. I don't know if we'll get there. I hope we do."), 9 ("We did not believe that the commercial contracts that we have in place would largely be affected mostly because they were already paying higher. . . So, I'm not overly concerned about [those contracts being adversely affected]."), 9 (Q: How does this impact your relationships with private payers and/or sort of the balance of your revenue base? . . . A: Look, I don't believe it does."), 10 ("I don't believe this is going to be a challenging process. It is going to take some time. . . The data is already available, the relationships are in place with numerous local carriers, and we'll try to contract with as many as possible to establish the right pricing level."), 11 ("[A]ll of the players in the space would point to the fact that having these fully integrated systems is what's important to be able to get the outcome that the code is looking for."), 13 (Q: "[W]hat can you see really driving Novitas' [future] payment higher?". . . A: "[T]here is substantial internal investment that has gone in the development of the advanced AI algorithms. . . So there are significant cost impacts—inputs that we simply can't provide the invoices for because we're doing them internally"), 14 ("We completely are ready to re-engage Novitas as they see fit for expansion of the discussion"), 15 ("So coming up with alternative methodologies that actually will look not just at those direct product costs, but the broader variable cost that go into providing the service. . . that need to reflected in the calculation of the cost. . . We are now suggesting [alternative models] would be

Lead Plaintiff argues these statements are not exclusively forward-looking because they are "mixed statements" that include "current statements of historical fact." Opp. at 23-24. "The PSLRA's safe harbor is designed to protect companies and their officials from suit when optimistic projections of growth in revenues and earnings are not borne out by events." *In re Quality Sys., Inc. Sec. Litig.*, 865 F.3d 1130, 1142 (9th Cir. 2017). "But the safe harbor is not designed to protect companies and their officials when they knowingly make a materially false or misleading statement about current or past facts." *Id.* "Nor is the safe harbor designed to protect them when they make a materially false or misleading statement about current or past facts, and combine that statement with a forward-looking statement." *Id.* Nonetheless, even if a portion of a challenged statement includes a non-forward-looking statement, it is covered by the safe harbor provision if "examined as a whole, the challenged statement[] relate[s] to future expectations and performance." *Police Ret. Sys.*, 759 F.3d at 1059; *id.* (current statement of historical fact that "at the present time, we don't have any indicators that tell us that's the case" was properly classified as an assumption underlying or related to future projections of expenditures). This is because the safe harbor immunizes assumptions "underlying or related to" any forward-looking statement. 15 U.S.C. § 78u(i)(1).

Thus, "in order to establish that a challenged statement contains non-forward-looking features that avoid this definition, a plaintiff must plead sufficient facts to show that the statement goes beyond the articulation of 'plans,' 'objectives,' and 'assumptions' and instead contains an express or implied 'concrete' assertion concerning a specific 'current or past fact[ ].'" *Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1191 (9th Cir. 2021) (citing *Quality Systems*, 865 F.3d at 1142, 1144). In *Wochos*, the court found that "Tesla's various statements that it was 'on track' to achieve this

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appropriate models to relook at."), 16 ("I think the Novitas has basically seen this as a viable path for being able to address what they want to get to. . . Meetings are being scheduled – have been scheduled, will be over the next several weeks, talking to multiple constituents both among the MACs as well as with CMS."), 17 ("I can definitely assure that everything has stayed on track to our expectation. . . And this does not in any way reflect the difference in our opinion on what the outcome and what the chances of how we'd be handicapping the chances of various outcomes in the reimbursement process."), 18 ("As I mentioned, the cost models that we're moving to. . . we're not reinventing the wheel here, we're not trying to move into unbroken ground. We're trying to leverage best practices.").

goal and that 'there are no issues' that 'would prevent' Tesla from achieving the goal [were] forward-looking statements. . . because any announced "objective" for "future operations" necessarily reflects an implicit assertion that the goal is achievable based on current circumstances." *Id*. By contrast, in *Quality Systems*, the defendants' affirmative statements that the defendant company's current sales and performance were comparable to those in the past were not forward-looking because they "provided a concrete description of the past and present state of the [company's sales] pipeline." 865 F.3d at 1143-44.

Here, Plaintiff includes a list of fragments from the statements Defendants contend are forward-looking, and asserts that these fragments indicate "current statements of historical fact" that are immunized from the PSLRA's safe harbor. Opp. at 23-24. However, Plaintiff provides no analysis as to why these fragments are not predicate assumptions covered by the safe harbor, or why the statement, when "examined as a whole" do not amount to a forward-looking statement. *Police Ret. Sys*., 759 F.3d at 1059. For example, Plaintiff challenges the statements that: "the [CMS] process was so thorough and so complete, I'm hoping there's not much to change"; "there is no substance of news, progress has been good"; and "things have been very stable" in negotiating with commercial payors. Statement Nos. 3, 17; Opp. at 23, 24. Each is protected by the safe harbor because they are too vague to constitute a "concrete description" of present facts, and because, to the extent they reference a past action, the reference is solely as an assumption for a forward-looking projection about the outcome of the rate-setting process. *Wochos*, 985 F.3d at 1196*; see also Murphy v. Precision Castparts Corp*., 2021 WL 2080016, at *5 (D. Or. May 24, 2021) (applying *Wochos*; "a company must disclose that it reached a specific benchmark for the statement to be actionable, not that it reached an undisclosed or non-specific benchmark"); *Police Ret. Sys*., 759 F.3d at 1059.

Additionally, Plaintiff challenges Defendants' statements about advocating for higher pricing to Novitas by describing historical costs associated with "deep learned algorithms," "technology," "software," and "database" support. Opp. at 24; Statement No. 15. But the face of the statement clearly indicates that the speaker, Defendant Coyle, was describing the variables that the company wanted Novitas to incorporate in the future when calculating the reimbursement rate

for Zio XT. The portion of the statement Plaintiff points to is connected to Defendants' "plans" and "objectives" for how they hoped the reimbursement rate would be calculated. Taken as a whole, Statement No. 15 is forward-looking.

Similarly, Plaintiff objects to the portion of Statement No. 6 in which Defendant King notes "we believe our commercial contract pricing is unaffected." But this fragment is not a statement of current or historical fact; rather it is embedded in a response in which King is responding to an analyst inquiry about the company's outlook in light of CMS's Final Rule announcement the day before in which the agency declined to set a national rate for Zio XT. *See* SAC ¶ 158. Defendant King is discussing his projections for how the rule announcement will affect the company's revenue streams, and predicts that the rule announcement will not affect "commercial contract pricing." *Id*. The statement, as a whole, is future-looking. *Police Ret. Sys*., 759 F.3d at 1058 ("The alleged misstatements in analyst calls are classic growth and revenue projections, which are forward-looking on their face.").

Only one objection Plaintiff advances suffices to demonstrate a "concrete" assertion of past or current fact beyond the definition of a "future-looking" statement for the purpose of the safe harbor. First, Defendants' statement that "we provided over 500,000 invoices to CMS for our service across a wide range of contracted arrangements, commercial carriers, noncommercial carriers, patients have paid out of pocket, CMS rates, and everything," is not protected by the safe harbor. Statement No. 1. This portion of the statement is substantially similar to challenged Statement No. 2, which Defendants do not argue is future looking. These statements are analyzed later.

Thus, Statement Nos. 1 (other than the portion excerpted above), 3-11 and 13-18 are forward-looking.

b. Meaningful Cautionary Language

The PSLRA immunizes forward-looking statements "if they were identified as forward-looking statements and accompanied by meaningful cautionary language." *Park v. GoPro, Inc.*, 2019 WL 1231175, at *15.

Here, Defendants provided specific and detailed cautionary language regarding the limits

to its predictions of the ultimate outcome of CMS and Novitas' rate-setting process, and continuously updated their warnings to the public throughout the class period. As already discussed, at the outset of the class period, iRhythm's Form 10-Q, publicly filed with the SEC, provided extensive warnings regarding the uncertainty and potential impact of the CMS's rule-making. *See supra* Discussion § C(1); Docket No. 55-1, Exh. 3 at 43 ("We can provide no assurance that any Category I CPT code secured for the reimbursement of our Zio service will contain values and pricing that are the same as or greater than the existing Category III CPT codes. In addition, to the extent CMS reduces its reimbursement rates for the Zio service, regardless of the Category of CPT code, third-party payors may reduce the rates at which they reimburse the Zio service, which could adversely affect our revenue."). During the August 4, 2020 call with investors (from which challenged Statement No. 1 is drawn), Defendants stated, "The issuance of the proposed rule is followed by a public comment period that closes on October 5, 2020 and will culminate in the CMS' final rule. . . Therefore, the proposed rule is subject to change." Docket No. 55-1, Exh. 9 at 4. *See also* Statement Nos. 3 ("I'm hoping there's not much to change. But of course, there's the comment period. And we'll see what happens."); 5 ("[W]e're looking very forward to December 1st when the final ruling takes place.").

Later, Defendants' November 6, 2020 Form 10-Q Filing, issued prior to CMS's announcement of its final rule, the company stated, "[w]hile CMS's proposed reimbursement for the Category I CPT codes . . . was higher than their associated Category III CPT codes, we can provide no assurance that the reimbursement CMS proposed . . . will not be reduced by CMS in its final ruling." *Id.*, Exh. 2 at 41. *See also* Statement No. 4 ("The initial ruling was put out by CMS on August 4 and 5. . . It is an initial ruling, so there's the comment period that place between now and sometime in early December, before it becomes final.").

After CMS issued its final rule declining to set a national rate for Zio XT and delegating authority back to Novitas, Defendants expressed uncertainty when speaking publicly as to the prospect of maintaining and increasing the reimbursement rate. *See* Appendix A, Statement Nos. 8 ("We're going to be shooting for that higher end of where we were. I don't know if we'll get there. I hope we do."); 7("We intend to continue to collaborate with them and try to push this

forward.").

After Novitas announced reduced reimbursement rates in January 2021, Defendants' next SEC filing 10-K Filing (filed February 26, 2021) explained that the rates "were significantly below our historical Medicare rates for Zio XT" and cautioned that the company was "in the process of negotiating with Novitas to establish higher pricing for the Category I CPT Codes but [could] offer no assurances as to timing or outcome of those decisions." Docket No. 55-1, Exh. 1 at 34-35. The company warned that if Novitas did not raise rates, it "may be unable to provide the Zio XT service or would experience a significant loss of revenue." *Id.*

And as the company prepared for CMS's notice of proposed rule to set reimbursement rates for 2022, Defendants informed investors that they "continue to take good meeting and have good dialog with multiple MACs and CMS" but warned that "the number of meetings with a number of different entities . . . does not in any way reflect the difference in our opinion on what the outcome and what the chances of how we'd be handicapping the chances of various outcomes in the reimbursement process." Statement No. 17.

These statements are the kinds of specific and meaningful cautionary language that trigger the protection of the safe harbor. *See e.g.*, *GoPro*, 2019 WL 12311755, at *16 (cautionary language that "a decline in the price or unit demand of our top-selling [products] . . . could materially harm our business or operating results"); *In re. Sanofi Securities Litigation*, 87 F. Supp. 3d 510, 535–36 (S.D.N.Y. 2015) (cautionary language that "[a] regulatory authority may deny or delay an approval because it was not satisfied with the structure or conduct of clinical trials").

Moreover, each public call with investors in which Defendants' engaged began with a series of warnings, along the lines of the following; "All forward-looking statements, including, without limitation, those statements related to CPT coding decisions, our expectations regarding government and third-party payer adoption of CPT coding decisions and the timing thereof and other statements relating to reimbursement coverage, these statements involve material risks and uncertainties that could cause actual results or events to materially differ from those anticipated or implied by these forward-looking statements. Accordingly, you should not place undue reliance on these statements." *See* Docket No. 55-1, Exh. 9 at 4 (Aug. 4, 2020 call); *id.*, Exh. 6 (Dec. 2,

2020 call) at 4 (similar); *id.*, Exh. 7 (Nov. 5, 2020 call) at 2-3 (similar). The Ninth Circuit has repeatedly found similar language sufficiently cautionary to trigger the forward-looking statement exemption under the PSLRA's safe harbor provision. *See In re Cutera Sec. Litig.*, 610 F.3d 1103, 1112 (9th Cir. 2010) (finding the following language sufficiently cautionary: "Cutera's January 31 conference call began with a notice that 'these prepared remarks contain forward-looking statements concerning future financial performance and guidance,' that 'management may make additional forward-looking statements in response to[ ] questions,' and that factors like Cutera's 'ability to continue increasing sales performance worldwide' could cause variance in the results."); *Police Ret. Sys.*, 759 F.3d at 1059-60 ("This cautionary language is virtually identical to the cautionary language approved in *Cutera*. . . [Therefore], the forward-looking statements are exempt under the PSLRA's safe harbor provision.").

Plaintiff does not respond in substance to Defendants' arguments that their forward-looking statements were accompanied with meaningful cautionary warnings. Instead, the entirety of their response is the following:

> Virtually all so-called cautionary statements refer to alleged risks that "could" or "may" happen when the risks had already materialized. This is not enough to escape liability. *See In re Alphabet, Inc. Sec. Litig.*, 1 F.4th 687, 703–04 (9th Cir. 2021).

Opp. at 24. But Plaintiff does not identify the risks that purportedly "already materialized." The relevant risks were whether CMS or Novitas would adopt rates lower than Defendants sought. But Defendants warned of the risks that the rate settings *could* yield outcomes lower than Defendants hoped *before* the rates were decided, and disclosed those decisions when they were announced. Plaintiff does not allege that Defendants *knew* of the adverse rate decisions and withheld that information; there are no allegations that the rate decisions were announced to Defendants prior to the point that they were announced the public. Moreover, while Plaintiff seeks to advance its theory that Defendants were *certain* that their reimbursement rates would be slashed through the regulatory process, this argument runs afoul of *Epstein*'s controlling analysis: "**[**R]eliance on predictive statements in the context of regulatory proceedings is inherently unreasonable. Basing an investment decision on an anticipated and contingent outcome of a

litigated regulatory proceeding, even *with* full knowledge of the prior history of the parties, is tantamount to sheer speculation; and guessing wrong hardly suggests fraud." 83 F.3d at 1141-42.

Thus, Statement Nos. 1 (with the exception of the portion re 500,000 invoices), 3-11, 13-18 are forward-looking statement that were accompanied by sufficiently meaningful cautionary language, and, thus, are not actionable because they are protected by the PSLRA's safe harbor provision.

3. Remaining Challenged Statements Are Not Material Misrepresentations

After determining that most of the challenged statements are forward-looking and protected by the PSLRA's safe harbor, the Court is left to consider Statement Nos. 1 (partially), 2 and 12. The SAC, however, fails to state claims on the basis of these statements because it fails to establish the materiality of those statements. *Halliburton Co.*, 134 S.Ct. at 2407. To meet the materiality requirement of Rule 10b–5, the complaint must allege facts sufficient to support the inference that there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." *Levinson*, 485 U.S. at 231–32 (internal quotation marks omitted).

a. Statement Nos. 1-2

The SAC alleges Defendant King misrepresented the completeness of iRhythm's data submissions to CMS in calls with investors on August 4, 2020 and August 6, 2020, shortly after CMS released its proposed rule. Appendix A, Statement Nos. 1 ("And so we worked hand-in-hand, as referenced in the CMS note, and we provided over 500,000 invoices to CMS for our service across a wide range of contracted arrangements, commercial carriers, noncommercial carriers, patients have paid out of pocket, CMS rates and everything, those were all used."), 2 ("As I said on the call, I think it was yesterday, we provided to CMS over 500,000 invoices for our service across contracted, non-contracted, Medicare, self-pay, client bill. . . And they have everything they can get from us.").

The SAC argues that these Statements "were materially false and misleading when made because. . . iRhythm did not provide any 'invoices' (let alone 500,00) as King falsely claimed, but instead provided only claims data that was inadequate and could not substitute for the actual

invoices." SAC ¶ 149. This argument references the SAC's theory that iRhythm failed to disclose that it refused to comply with CMS's request for an "invoice" that showed the component costs of the Zio XT service, such as the cost of the hardware on its own. The SAC further alleges that the statements omitted relevant details that would have shown that Defendants were unlikely to succeed in obtaining their favored rate from CMS. *Id.*

These allegations miss the mark to plausibly plead falsity or a material misrepresentation. The SAC fixates on King's use of the word "invoice" to contend that he falsely claimed to provide a specific "invoice" showing a breakdown of the cost of the component parts of the Zio XT service, but ignores the surrounding context of the statement which expressly shows that King was not using the word "invoice" in that manner. King expressly stated that the 500,000 invoices covered "a wide range of contracted arrangements, commercial carriers, noncommercial carriers, patients have paid out of pocket, CMS rates" and "contracted, non-contracted, Medicare, self-pay, client bill." Statements Nos. 1, 2. King expressly noted that iRhythm did *not* generate invoices that showed component costs, because "our business model is not a typical business model in that we are developer, the manufacturer, the supplier and provider of the service[,] [s]o there is not sale of iRhythm to iRhythm, [i]t's just one integrated service." Statement No. 1. King expressly noted that the invoices iRhythm provided were designed to help CMS "find something that was equivalent in supply cost" and stated he "th[ought] that calculation was well done." *Id.*

Moreover, both of the calls from which these statements are pulled occurred *after* CMS publicly released its proposed rule, which expressly disclosed that "CMS did not receive a traditional invoice to establish a price." 85 Fed. Reg. 50165. Indeed, the SAC acknowledges that questions to which Defendant King was responding were expressly following up on CMS's statement that the agency lacked a "traditional invoice." *See* SAC ¶ 148 ("Q: And [CMS] also say that. . . they do not have – I forget what the words were – they don't have invoicing for extended patch monitors."), ¶ 149 (Q: "I presume you will be supplying the invoices for various components to CMS before the final reimbursement rule comes out."). Put differently, the only reasons Defendant King was addressing the topic of invoices is because CMS publicly disclosed that it had not received traditional invoices that show component costs; King provided his

explanation for what data iRhythm *did* submit. In light of this context, Statement Nos. 1 and 2 cannot plausibly have misled investors into thinking that Defendants had submitted invoices showing components costs for the Zio XT. *See Heliotrope General, Inc. v. Ford Motor Co.*, 189 F.3d 971, 975–76, 980–81 (9th Cir. 1999) (omission is not actionable if omitted information has already entered the market).

Finally, the SAC's contention that Statements Nos. 1, 2 are rife with materially misleading omissions because they do not disclose a host of potential problems with iRhythm's quest to maintain its reimbursement rate – *see* SAC ¶¶ 149, 151 – are unpersuasive. The statements respond to pointed questions about the data that iRhythm had submitted or would submit to CMS with regards to the comment in the proposed rule that the agency lacked a traditional invoice. Defendant King was not obligated to identify all of the potential risks iRhythm faced in securing the reimbursement rate it sought when answering these questions and describing the data iRhythm had or intended to submit in order to make an accurate and non-misleading representation.

Thus, the SAC fails to state claims arising from Statement Nos. 1, 2 because those statements are not materially misleading.

b. Statement No. 12

The SAC challenges Statement No. 12, derived from iRhythm's Form 10-K, publicly filed with the SEC on February 26, 2021. SAC ¶ 171. Specifically, the SAC challenges the following:

> [P]olicy affecting Medicare coverage and reimbursement relative to our Zio service ***could*** have a material effect on our performance. . . [C]hanges to the coverage, method and level of reimbursement for our Zio service ***may*** affect future revenue. . . [C]hanges in public health insurance coverage and CMS reimbursements for the Zio XT service ***could*** affect the adoption and profitability of our Zio service.

Id. The SAC argues, "Such statements were materially false and misleading when made because many of these risks had ***already*** materialized, including a massive rate cut initiated by Novitas in January 2021, and Defendants had no legitimate basis to seek inflated reimbursement rates from CMS or the MACs before such false statements were made." *Id.*

These arguments are not persuasive. The SAC ignores that the *very same filing* stated, "[o]n January 29, 2021, Novitas Solutions . . . published rates for 2021 that were significantly

below our historical Medicare rates" and "[i]f the published rates by Novitas remain unchanged or are not significantly improved . . . we may be unable to provide the Zio XT service or would experience a significant loss of revenue[.]" Docket No. 55-1, Exh. 1 at 34–35. Thus, the SAC cannot fairly assert that Defendants failed to disclose Novitas's rate cut; they did exactly that. *McGovney v. Aerohive Networks, Inc.*, 367 F. Supp. 3d 1038, 1056 (N.D. Cal. 2019) (claims failed where company "disclose[d] exactly what Plaintiffs claim" it omitted).

Thus, the SAC fails to state a claim arising from Statement Nos. 12 because that statement is not materially misleading.

4. Conclusion re Allegations of Material Misrepresentations

In sum, the Court concludes that none of the 18 challenged statements identified in the SAC are actionable. Statements 1 (partially), 3-11, 13-18 are protected by the PSLRA's safe harbor, and Statements 1, 2 and 12 do not contain material misrepresentations.

As such, it is worth underscoring the defect that infects the guiding theory of the entire complaint. The SAC's allegations of fraud *all* derive from the core premise that Defendants had *knowledge* that their efforts to obtain a favorable reimbursement rate were destined to fail, and that Defendants *should* have sought *only* a reimbursement rate in line with the amount advocated for in the MCDA report. Both a summary of the particular facts here and relevant case law belie the SAC's central theory.

The sequence of regulatory decisions contradicts the SAC's theory that the regulatory outcome was knowable and absolutely certain. For several years iRhythm received a reimbursement rate in excess of $300 under the Category III codes set for the Zio XT service while the product remained categorized as a new technology. In 2020, the AMA recommended recognizing long-term AECG devices like Zio XT as the "standard of care" and assigning a permanent Category I code and price for the service. This recommendation and recognition were channeled into a proposed rule by CMS in August 2020 that indicated the agency's intention to *increase* the reimbursement rate for the service to $386. The notice and comment period that followed the proposed rulemaking drew differing opinions, including MCDA's submission arguing for a rate of less than 25% of CMS's proposal. In December 2020, CMS declined to

adopt a national rate for the Zio XT service for 2021, and, instead, delegated the rate-setting to Novitas, the same contractor that, for years, had set the Category III rate in excess of $300. In January 2021, Novitas announced a rate between $73 and $89. But, then, in April 2021, Novitas revised its rate upwards by upwards of 30% to an average of $115. Thereafter, in November 2021, CMS announced its final rule for rates in 2022, and endorsed a rate of over $200 to be considered by MACs like Novitas. 86 Fed. Reg. 65125. Finally, Novitas adopted rates for 2022 in excess for $210. *See* Docket No. 59-1, Exh. 24.

As this history shows, the regulatory process is unpredictable. Regarding this, Defendants consistently and accurately warned investors throughout this volatile period of rate fluctuations that they could not assure any particular outcome as to final rate decisions and that low rates would adversely affect the company's revenue and outlook. Nonetheless, the SAC alleges Defendants engaged in fraud because they had *certainty* that their attempts to seek favorable reimbursement rates were *futile*, and, moreover, that Defendants *knew* that they could not obtain rates any better than those proposed by third-parties with differing opinions, such as MCDA. The facts here – immense swings through iterative regulatory processes between temporary rates, proposed rates and actual rates – simply do not support this assertion.

Nor does the law. As discussed at length, the Ninth Circuit's decision in *Epstein* acknowledges the uncertainty inherent in the outcome of regulatory proceedings, and, thus, warns that "[b]asing an investment decision on an anticipated and contingent outcome of a litigated regulatory proceeding, even with full knowledge of the prior history of the parties, is tantamount to sheer speculation; and guessing wrong hardly suggests fraud." 83. F.3d at 1141. Even outside of the regulatory context, courts have dismissed claims of fraud based on second-guessing statements in hindsight predicated on differences in opinion. *See, e.g., City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 65 F. Supp. 3d 840, 852–53 (N.D. Cal. 2014) (rejecting plaintiff's allegation that impairment analysis in financial statement was false when based solely on plaintiff's "own calculation" of what value "should have been" representing only "a difference of opinion" over that value); *Mulquin v. Nektar Therapeutics*, 510 F. Supp. 3d 854, 866–67 (N.D. Cal. 2020) (allegations that company violated "clear industry and scientific norms

against both the presentation of 'highly incomplete' and 'outlier-driven' data" not credited); *In re Restoration Robotics, Inc. Sec. Litig.*, 417 F. Supp. 3d 1242, 1260 (N.D. Cal. 2019) ("'reasonable persons may disagree over how to analyze data and interpret results'"); *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d Cir. 2016) (allegations that amount to "a dispute about the proper interpretation of data" fail to state a claim); *Harris v. AmTrust Fin. Servs., Inc.*, 135 F. Supp. 3d 155, 173 (S.D.N.Y. 2015) (dismissing action where plaintiff "at best. . . alleges a difference of opinion" based on disagreement with assumptions and inputs); *In re Sierra Wireless, Inc. Sec. Litig.*, 482 F. Supp. 2d 365, 367 (S.D.N.Y. 2007) ("The securities laws neither require corporate officers to adopt a crabbed, defeatist view of the company's business prospects nor permit dissatisfied shareholders to assert serious allegations of fraud based on the perfect hindsight afforded by the passage of time"); *cf. Ronconi v. Larkin*, 253 F.3d 423, 434 (9th Cir. 2001) ("Problems and difficulties are the daily work of business people. That they exist does not make a lie out of any of the alleged false statements. So far, there is not much more to the case beyond the facts that (1) two companies merge, expecting to increase profits in significant part by using fewer salespeople than their combined total, because their products and markets are related; (2) they fire a lot of salespeople; and (3) this is not as productive a maneuver as they had hoped. The third proposition can be true without the first being false.").

Thus, Defendants' attempts to obtain the highest reimbursement rates they could—while warning investors that they could not guarantee any particular outcome of the regulatory process—does not give rise to a cause of action for fraud. The Ninth Circuit summarized the flaw in a similar theory in *Nguyen*:

> The central theory of the complaint is thus that defendants knew the FDA would not approve Nellix, or at least that it would not do so on the timeline defendants were telling the market. . . These allegations encounter an immediate first-level problem: why would defendants promise the market that the FDA would approve Nellix if defendants knew the FDA would eventually figure out that Nellix could not be approved due to "intractable" and "unresolvable" device migration problems? The theory does not make a whole lot of sense. It depends on the supposition that defendants would rather keep the stock price high for a time and then face the inevitable fallout once Nellix's "unsolvable" migration problem was revealed. If defendants had sought to profit from this scheme in the interim, such as by selling off their stock or selling the company at a

> premium, the theory might have more legs. *See, e.g., In re Rigel Pharm., Inc. Sec. Litig.*, 697 F.3d 869, 884–85 (9th Cir. 2012). There are no factual allegations like that here. Instead, we are asked to accept the theory that defendants were promising FDA approval for a medical device application they knew was "unapprovable," misleading the market all the way up to the point that defendants were "unable to avoid the inevitable." The allegation does not resonate in common experience. And the PSLRA neither allows nor requires us to check our disbelief at the door.

962 F.3d at 414-15. This reasoning applies with equal force here. The theory of Plaintiff's case lacks logic.

In short, the statements challenged in the SAC are not actionable for claims of securities fraud.

D. Scienter

The Court determines that none of the 18 challenged statements are actionable because they are protected by the safe harbor provisions of the PSLRA or do not constitute material misrepresentations. Thus, the SAC fails to state claims, and the Court is under no obligation to further analyze the claims. *See, e.g., re Netflix, Inc. Sec. Litig.*, 2014 WL 212564, at *2 (N.D. Cal. Jan. 17, 2014). Nonetheless, even if Plaintiff had sufficiently pleaded material misrepresentation, the SAC fails for another independent reason: it does not allege facts to support a strong inference of scienter. "Scienter is a mental state embracing intent to deceive, manipulate, or defraud." *Intuitive Surgical*, 759 F.3d at 1061 (citation omitted). It is not enough to allege facts from which an inference of scienter "*could* be drawn," but rather, a plaintiff must "plead with particularity facts that give rise to a 'strong'—*i.e.*, powerful or cogent—inference." *Tellabs*, 551 U.S. at 323. "[T]he PSLRA's 'strong inference' requirement has teeth," and it is "an 'exacting' pleading obligation . . . that 'presents no small hurdle for the securities fraud plaintiff.'" *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 414 (9th Cir. 2020) (citation omitted). Plaintiff has not plead enough to meet this elevated standard.

1. Confidential Witness Allegations

The SAC includes allegations from CW1, who allegedly "strategized and oversaw the Company's policies and practices for seeking reimbursement." SAC ¶ 15. CW1 alleges that iRhythm hired an outside expert in 2017 who told the company that it would face a "major

challenge" to maintain its reimbursement rates before CMS, and that CMS would be "laser focused on breaking down the core costs of the [Zio XT] service." *Id.* ¶ 201. This allegation, however, demonstrates, at most, that Defendants were aware that it *could* be difficult to maintain their desired reimbursement rate – not that any Defendants ever held the belief that the Company would fail in its efforts, nor that Defendants intended to deceive investors by seeking its preferred reimbursement rate in spite of the obstacles. *See, e.g., Wochos*, 985 F.3d at 1194 ("Plaintiffs' allegations that '[s]uppliers had informed Tesla that the production timelines were impossible' do not establish that Defendants (who were still in the process of choosing suppliers) *shared* that gloomy view.") (emphasis in the original). Moreover, the allegations in the SAC imply that Defendants were not wrong to weigh the 2017 opinion of the outside expert against other considerations: despite the expert's warning in 2017, iRhythm maintained or increased its reimbursement rates before CMS between 2017 and 2020. Nothing in the SAC suggests that the expert's warning applied *only* to when iRhythm moved from a temporary to permanent CPT code. That the expert's cautionary warnings and opinion in 2017 was not borne out over the course of several years further diminishes the expert's years-old warning as a fact giving rise to a strong, cogent inference of scienter.

Similarly, CW1 alleges that Defendants were informed in February 2021 that an executive from Novitas stated that Novitas would only consider the Company's proposed pricing methodology if they could convince other Medicare Approved Contractors in other regions to accept the methodology as well. *Id.* ¶ 204. Again, this allegation, at most, demonstrates that Defendants faced obstacles to obtaining their desired reimbursement rates, but does not support an inference that Defendants "embrac[ed] [an] intent to deceive, manipulate, or defraud" by, nonetheless, taking on those obstacles and seeking a higher reimbursement rate. *Intuitive Surgical*, 759 F.3d at 1061. Indeed, Defendants repeatedly cautioned investors of the indeterminacy of the rate-setting process, consistent with the obstacles that Plaintiff alleged Defendants faced.

Plaintiff's citation to *Schueneman v. Arena Pharms., Inc.*, does not alter the analysis. 840 F.3d 698, 707 (9th Cir. 2016). In that putative class action securities fraud case, the Ninth Circuit

found Plaintiffs had alleged scienter with sufficient particularity to survive a motion to dismiss because Plaintiffs alleged that the defendant pharmaceutical company made *affirmative* misrepresentations to shareholders about the substance of its engagement with the federal Food and Drug Administration while it awaited regulatory approval. *Id.* The court summarized:

> Arena did more than just express its confidence in lorcaserin's future. It affirmatively represented that "all the animal studies that [had] been completed" supported Arena's case for approval. And at the time these statements were made by various Arena officials in 2009, Arena knew that the animal studies were *the* sticking point with the FDA. Contrary to Arena's representations to investors, it was not true that the "preclinical, animal studies" demonstrated the "long-term safety and efficacy" of lorcaserin or "the potential risk that [it] may be toxic or cause cancer in humans." It was also not true that Arena had "all of the data in hand" or that "everything that [they had] compiled so far" was "favorable." These statements were representations about lorcaserin that Arena could not, in fact, support at the time they were made. Arena was free to express confidence in FDA approval. It might have represented that Arena was working through some requests from the FDA and was confident the data would vindicate lorcaserin. But what it could not do was express confidence by claiming that all of the data was running in lorcaserin's favor. It was not.

Id. at 708. The SAC contains no comparable allegations that Defendants "affirmatively represented" information about studies, analyses or other predicate requirements for regulatory approval that had not, in fact, been completed. *Id.* The SAC contains no allegations that Defendants made untrue statements representing all of its submissions to CMS and Novitas as "favorable," when in fact, they were not. *Id.* Indeed, the SAC *could not* include such allegations because the challenged statements themselves reveal that Defendants did not make firm representations about the regulatory rate setting process because Defendants consistently cautioned investors that they could not predict how the agency would receive their arguments or how the rate-setting process would unfold.[3] *Id.* At most, the challenged statements reflect

[3] *See, e.g.*, Appendix A, Statement No. 7 ("I think the challenge is, as I described, CMS has a rather rigid framework that requires precise inputs like an invoice that don't exist in these categories. And it's our job to help them to remodel or to affect change such that not only iRhythm, but every other digital health company and every other subscription service company and healthcare, can get the benefit of fairly valued renumeration."), 8 ("And now we have new data that came out of the initial ruling that we intend to use. So, that gives me confidence that we're going to be -- we're going to be shooting for that for the higher end of where we were. I don't know if we'll get there. I hope we do."), 11 ("And all of the players in the space would point

Defendants' "confidence in [CMS] approval" and that Defendants were "working through some requests from [CMS] and was confident the data would vindicate [their requested rate]." *Id.*[4] Such comments are precisely the type that *Scheuneman* noted were permissible and did not give rise to a strong inference of scienter. *Id.*

2. CMS's Rejection of a Similar Cost Methodology in 2008

The SAC alleges that an inference of scienter should be drawn from the fact that CMS allegedly rejected an integrated cost methodology, similar to the one that Ds advanced in support of their proposed reimbursement rates, when a different company proposed such an approach in 2008. SAC ¶¶ 185-88. But the Ninth Circuit in *Epstein* expressly rejected the argument that a regulated company is liable for fraud by advancing a pricing proposal in regulatory proceedings that had been previously rejected by the regulatory body. In fact, in *Epstein*, the regulated company advanced the *very same* pricing scheme that the company *itself* had previously argued unsuccessfully. Here, the SAC alleges that the pricing scheme Defendants advanced was *similar*

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to the fact that having these fully integrated systems is what's important to be able to get the outcome that the code is looking for."), 14 ("[W]e have made additional proposals here in terms of how to think about the establishment of value for these particular codes and we are anxious to engage Medicare on that topic."), 16 ("So that ability to have the patient identified the first time with the appropriate arrhythmias and then allow them to be treated without a lot of waste in the system is what we're kind of pointing them to. .. And that's exactly where we are in discussions with them, that we think can take this first step and get us to a more reasonable representation of the true products and providing the service."), 18 ("In terms of the outcomes, I think we've talked about it in the earnings release as thoroughly as we can. And I'm confident we're doing the right things, but at the same time as I emphasized before, there the transparency on how the final decisions are made is very limited, and we're going to find out about things at the same time that the rest of you do.").

[4] *See, e.g.,* Appendix A, Statement Nos. 1 ("I think that calculation was done well, and we'll support it. And I'm confident it's what CMS wanted, and that's where we've got the rates."), 4 ("We've always been confident that our reimbursement rate will be the same or go up. And we believe, it stood the evidence in the fact base that we have. So we're really, really happy with that. It is an initial ruling, so there's a comment period that takes place between now and sometime in early December, before it becomes final."), 5 ("We remain extremely confident in where we sit. We've provided all of the necessary information and feedback, and we're looking very forward to December 1st when the final ruling takes place."). The question to which Defendant responded was "other than the commentary you've already provided in the public domain. . . how should we think about volume growth for this business?" Defendant then responded that he does not "have any other updated on reimbursement" beyond those in the prepared remarks and public disclosures since the proposed rule was announced – which included extended discussions about how iRhythm has structured the data it provided to CMS – so when Defendant said iRhythm "provided all of the necessary information," in that broader context, it was accurate.

to one argued by a *different company twelve years previously*.

3. Testimony from Delaware Litigation

The SAC argues that testimony introduced in a Delaware state court trial between two of iRhythm's competitors, Bardy and Hill-Rom, regarding a dispute over a merger agreement between the companies, demonstrates that "players in the industry understood the risks involved" in CMS's rate-setting process. SAC ¶¶ 191-197. Again, these allegations are consistent with iRhythm's express warnings to investors throughout the regulatory process that it could not guarantee the outcome of the rate-setting process and that lower rates would adversely affect the company's revenue.

4. Defendant King's Stock Sales

The SAC alleges an inference of scienter flows from the fact that that Defendant King allegedly engaged in insider trading by selling of stocks during the class period. SAC ¶¶ 214-16. These allegations fail because SEC Rule 10b5-1 permits the sale of stock according to a written plan of pre-established criteria eliminating discretion over trading, under which all of King's trades were made. *See* Exh. 18 at 2 n.1.

5. Conclusion re Scienter

For all the reasons discussed above, the SAC fails to plausibly allege a strong inference of scienter. This failure constitutes an additional and independent basis on which the Court dismisses the SAC for failure to state claims.[5]

E. Leave to Amend

As explained at length above, none of the 18 statements challenged in the SAC are actionable. The theory of fraud underlying the entire complaint fails as a matter of fact and law. And, even if Plaintiff had alleged any actionable statements, the theory of scienter is insufficient to support a strong inference. Thus, without any statements on which to support the SAC's claims nor any viable theories upon which to build such claims, the Court dismisses the complaint in its entirety. Moreover, because the central theory of the SAC is defective, any further amendment

[5] Accordingly, the Court need not address further arguments, such as to the sufficiency of SAC's loss causation allegations. *Netflix, Inc. Sec. Litig.*, 2014 WL 212564, at *2.

would be futile. Thus, the complaint is dismissed with prejudice. *See AmeriSourceBergen Corp. v. Dialysist W., Inc.*, 465 F.3d 946, 951 (9th Cir. 2006) ("[A] district court need not grant leave to amend where the amendment. . . is futile.").

IV. CONCLUSION

The Court **GRANTS** Defendants' motion to dismiss. Docket No. 55. Because Plaintiff's theory of fraud lacks support in facts and law, further amendment would be futile. Thus, the complaint is dismissed with prejudice.

This order disposes of Docket No. 55.

The Clerk of the Court is directed to enter judgment and close this case.

IT IS SO ORDERED.

Dated: March 31, 2022

EDWARD M. CHEN
United States District Judge

United States District Court
Northern District of California